

IN THE UNITED STATES DESIGNATED/ELECTED OFFICE

In re Application of:

Christos TSAKLAKIDS et al.

Examiner: Sun Jae Y Loewe

Serial No.: 10/551,557

Group Art Unit: 1626

Filed: October 3, 2005

Title: CARBONYL COMPOUNDS

PETITION UNDER 37 C.F.R. §1.181

TECHNOLOGY CENTER 1600

Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

Sir:

This is a petition requesting the Commissioner, through the Honorable Group Director, to reverse the Examiner's decision in not extending the search beyond the elected species, for making Final the Office Action of May 28, 2008, for denying entry of the amendments after Final submitted December 16, 2008, and for maintaining the Restriction Requirement which divided applicants' claims into 3 Groups. Specifically, applicants request that examination be performed on the entire scope of presently pending claims, that the Finality of the Office Action of May 28, 2008 be withdrawn, that the amendments submitted in the Reply under 37 CFR 1.116 filed December 16, 2008 be entered, and that the Restriction Requirement issued April 11, 2008 be withdrawn.

Statement of Facts

In the Office Action issued April 11, 2008, the Examiner presented a Restriction Requirement wherein the claims were divided into 3 Groups, i.e., Group I, drawn to compounds

of Formula I; Group II, drawn to a process for using said compounds; and Group III, drawn to a process of making said compounds. In addition, the Examiner made an Election of Species Requirement, regardless of which Group was elected. In support of the Restriction, the Examiner argued that the technical feature linking the Groups was a carbonyl group and asserted that this technical feature was widely taught in the prior art.

In the Response filed April 28, 2008, applicants elected Group I (compounds) and elected the species 1-N-[(4-chlorophenyl)]-2-N-[[4-(3-oxomorpholin-4-yl)phenyl]]-(2R,4R)-4-hydroxypyrrolidine-1,2-dicarboxamide. The applicants stated that claims 1-25, 29, 30, and 32 read on the elected species. Additionally, applicants argued that the claims of Groups I-III were a special group of categories of claims that are indicated, in section (e) of Annex B of the Administrative Instructions under the PCT, as satisfying the requirement of unity of invention. Thus, withdrawal of the Restriction was requested.

On May 28, 2008, the Examiner issued the first Office Action on the merits. In the Office Action, the Examiner acknowledged the elections made by the applicants on April 28, 2008. With regards to applicants' traversal of the Restriction, the Examiner stated that "there is not a special technical feature linking the inventions because the only commonality is a carbonyl groups, which is taught in the prior art." Claims 21, 24-26, 31, 33-42 were withdrawn from consideration as being directed to non-elected subject matter.

In the Office Action of May 28, 2008, the Examiner cited excerpts from MPEP 1893.03 and MPEP 803.02. In citing the excerpt from MPEP 803.02, the Examiner asserted that "the search and examination detailed in this office action was performed following the guidelines provided by MPEP 803.02."

Thereafter, the Examiner stated that the elected compound was not allowable and that the generic claims encompassing the elected species were also not allowable. The Examiner further stated that a **non-elected species** "was anticipated by the prior art." See page 4 of the May 28, 2008 Office Action.

The Office Action of May 28, 2008, presented several rejections. Claims 1-20, 22, 23, 29, and 30 were rejected under 35 USC 112, first paragraph. Claims 1-20, 22, 23, 29, and 30 were rejected under 35 USC 112, second paragraph. Claims 1-15, 17, 29, 30, and 32 were

rejected as being anticipated under 35 USC 102(e) in view of Bigge et al. (US 2003/0162787). Finally, Claims 1-20, 22, 23, 29, and 30 were rejected on grounds of Obviousness-type Double Patenting in view of claims 40-49 of Serial No. 11/575,711. Thus, the Office Action presented only one prior art rejection, i.e., the anticipation rejection in view of Bigge et al. (US 2003/0162787). Serial No. 11/575,711, having a US filing date of March 21, 2007, and an International filing date of August 24, 2005, is not prior art with respect to the instant application (the instant application has an International filing date of March 8, 2004).

In a Reply filed August 28, 2008, applicants responded to the Office Action of May 28, 2008. In the Reply, applicants amended claim 1 to incorporate the features of claim 16, a claim which read on the elected species and which was **not rejected in view of prior art** in the Office Action of May 28, 2008.

In the August 28, 2008 Reply, among other things, applicants requested clarification as to the scope of examination. In the May 28, 2008 Office Action the Examiner had stated that the elected compound was not allowable. Yet, the Office Action failed to present any rationale as to why the elected compound was not allowable. Specifically, in the August 28, 2008 Reply applicants stated:

However, the issue regarding examination in accordance with MPEP §803.2 is whether the elected species of the Markush claim is found to be anticipated or obvious by prior art. In the instant case, the Office Action does not demonstrate that the elected species of 1-N-[(4-chlorophenyl)]-2-N-[[4-(3-oxomorpholin-4-yl)-phenyl]]-(2R,4R)-4-hydroxypyrrolidine-1,2-dicarboxamide is anticipated or obvious in view of prior art. In fact, the only prior art rejection presented in the Office Action did not reject claim 16, which encompasses the elected species.

Applicants also requested reconsideration of the Restriction Requirement. Applicants argued that the Examiner's assertion that a carbonyl group was the only commonality did not address the rationale presented in Annex B, section (e). Applicants further argued:

Annex B, section (e) of the Administrative Instructions Under the PCT, clearly states that there **special groups of categories of claims that are considered as satisfying the requirement of unity of invention**. One of these groups is where there is an independent claim directed to product, and independent claim directed to a process for manufacturing the product, and an independent claim directed to a use of the product. This is the situation presented by the instant group of claims.

Asserting that the compounds of Group I have a carbonyl group as the only commonality does not refute the fact that the claims of Groups I-III are directed to a special category of claims that Annex B, section (e) states will be considered as satisfying the requirement of unity of invention.

Finally, in the August 28, 2008 Reply, applicants also traversed the rejections under 35 USC 112, first paragraph, 35 USC 112, second paragraph, 35 USC 102(e) in view of Bigge et al. (US 2003/0162787), and Obviousness-type Double Patenting.

Thereafter, the Examiner issued a Final Rejection on November 7, 2008. In this Office Action, the Examiner expressly withdrew the sole prior art rejection in view of Bigge et al. The Examiner maintained the rejections under 35 USC 112, first paragraph, and 35 USC 112, second paragraph. The Examiner also maintained the Obviousness-type Double Patenting because “there are other outstanding rejections maintained.”

On December 16, 2008, applicants filed a Reply under 37 CFR 1.116. Applicants requested entry of amendments to claims 1 and 23 to delete references to derivatives and solvates. Applicants stated that “These amendments place the claims in condition for allowance by rendering moot all pending rejections.”

Applicants also requested rejoinder of the withdrawn method claims pursuant to MPEP 821.04. Also, applicants argued that the elected species had not been shown to be anticipated or obvious by prior art, and that examination should proceed in accordance with MPEP §803.2. Clarification as to the scope of examination was again requested.

With respect to the rejections, applicants pointed out that the deletion of the terms solvates and derivatives rendered moot the rejections under 35 USC 112, first paragraph, and second paragraph, respectively. As for the obviousness-type double patenting rejection, applicants argued that all other grounds of rejection were rendered moot by the amendments, and thus the obviousness-type double patenting rejection should be withdrawn.

On January 6, 2009, the Examiner issued an Advisory Action denying entry of the amendments submitted December 16, 2008. In the Advisory Action, the Examiner asserted that the amendments raised new issues requiring further search and/or consideration. Specifically, the Examiner stated that:

Prosecution was limited to the elected species; withdrawal of grounds of rejection would necessitate rejoinder of non-elected species which requires further search and evaluation. (emphasis added)

Summary of Arguments in Support of Reversal of Denial to Extend the Search, Reversal of the Finality of the November 7, 2008 Office Action, Reversal of Denial of Entry of the Amendments after Final, and Denial of Withdrawal of the Restriction Requirement

1) Failure to Extend the Search and Finality of the November 7, 2008 Office Action

MPEP 803.02 states:

On the other hand, should the examiner determine that the elected species is allowable, the examination of the Markush-type claim will be extended. If prior art is then found that anticipates or renders obvious the Markush-type claim with respect to a *nonelected species*, the Markush-type claim shall be rejected and claims to the nonelected species held withdrawn from further consideration. The prior art search, however, will not be extended unnecessarily to cover all nonelected species. Should applicant, in response to this rejection of the Markush-type claim, overcome the rejection, as by amending the Markush-type claim to exclude the species anticipated or rendered obvious by the prior art, the amended Markush-type claim will be reexamined. The examination will be extended to the extent necessary to determine patentability of the Markush-type claim. In the event prior art is found during the reexamination that anticipates or renders obvious the amended Markush-type claim, the claim will be rejected and the action can be made final unless the examiner introduces a new ground of rejection that is neither necessitated by applicant's amendment of the claims nor based on information submitted in an information disclosure statement filed during the period set forth in 37 CFR 1.97(c) with the fee set forth in 37 CFR 1.17(p). See MPEP § 706.07(a). Amendments submitted after the final rejection further restricting the scope of the claim may be denied entry if they do not comply with the requirements of 37 CFR 1.116. See MPEP § 714.13.

During the entire prosecution of the instant application, the Examiner has never provided reasons why the elected compound was said to be not allowable. Claims which read on the elected species were clearly not rejected in view of prior art. The grounds of rejection under 35 USC 112 did not apply to **the elected species** *per se*. Even if one considers the provisional obviousness-type double patenting rejection, this rejection was not based on prior art. Additionally, if this provisional rejection were the only basis for rejecting **the elected species**, it

should have been withdrawn as there were no other rejections on **the elected species**.

Thus, in accordance with MPEP 803.02, examination of the Markush-type claim should have been extended. It is noted that in the May 28, 2008 Office Action, it appeared that examination was extended to a *nonelected species*, i.e., the species relied upon in the prior art rejection in view of Bigge et al. Applicants requested clarification as to the scope of examination, but did not receive such clarification.

In any event, in response to the prior art rejection of the *nonelected species*, applicants amended the claims to overcome the rejection. Thus, pursuant to MPEP 803.02, the amended Markush claim should have been reexamined. However, examination was not extended.

As noted in MPEP 803.02, if prior art is found during “the reexamination that anticipates or renders obvious the amended Markush-type claim, the claim will be rejected and the action can be made final.” However, the Final Office Action presented no prior art rejection that asserted that the Markush claim was anticipated or obvious.

For the reasons presented above, applicants respectfully request that the Examiner’s decision not to extend the search after applicants had amended the claim to eliminate the sole prior art rejection be reversed. Similarly, since examination was not performed in accordance with MPEP 803.02, applicants further request reversal of the Examiner’s decision to make the November 7, 2008 Office Action a Final Office Action.

2) Denial of Entry of the Amendments after Final

In the January 6, 2009 Advisory Action, the Examiner denied entry of certain amendments to the claims because it was asserted that “Prosecution was limited to the elected species,” and therefore “withdrawal of grounds of rejection would necessitate rejoinder of non-elected species which requires further search and evaluation.” Thus, the Examiner expressly states that examination was limited to only the elected species. Further, the Examiner implicitly indicated that the requested amendments would eliminate all pending grounds of rejection.

As discussed above, the Examiner’s failure to extend the search **prior** to the issuance of the Final Officer Action was improper. Thus, the rationale that the amendments are denied entry because it would require expansion of the search also is improper. The examination should have

been extended before the issuance of the Final Officer Action.

For the reasons presented above, applicants respectfully submit that the rationale presented in the Advisory Action does not justify denial of the entry of the amendments. Thus, applicants request reversal of the Examiner's decision not to enter the amendments presented in the Reply under 37 CFR 1.116 on December 16, 2008.

3) Denial of Withdrawal of the Restriction Requirement

As noted above, the initial Restriction Requirement divided the claims into 3 Groups, i.e., Group I, drawn to compounds of Formula I; Group II, drawn to a process for using said compounds; and Group III, drawn to a process of making said compounds. The Examiner argued that such a Restriction was proper under PCT Rule 13.1, because under PCT Rule 13.2, the claims were said to lack the same special technical feature. In this regard, the Examiner said the same technical feature was a carbonyl group and that such a feature was known in the art.

Firstly, as a result of amendments, the claims share a larger structural feature than just a carbonyl group. Specifically, in all the claims the compounds exhibit a -CONH-phenylene-morpholinyl group. See the definitions of X, Y and T in claim 1. Thus, the assertion that the only technical feature shared by the claims is a carbonyl group is no longer applicable. It is noted that this is the only argument asserted in support of the Restriction.

Secondly, the Restriction Requirement fails to take into account sections (d) and (e) of Annex B of the Administrative Instructions Under the PCT [See also paragraphs 10.11 and 10.12 of the PCT International Search and Preliminary Examination Guidelines]. Section (d) of Annex B clearly states that there are three particular situations regarding unity of invention under PCT Rule 13.2 and that for these three situations "the method for determining unity of invention contained in Rule 13.2 is explained in greater detail." The three situations are described in section (e) of Annex B. Section (e) B clearly states that there PCT Rule 13.2 shall be construed as permitting the inclusion of the following combination of claims: an independent claim directed to product, an independent claim directed to a process for manufacturing the product, and an independent claim directed to a use of the product. This is the situation presented by the Groups I-III of the Restriction Requirement.

Since the Restriction Requirement fails to use the methods of determining unity of invention under PCT Rule 13.2 as described in Annex B of the Administrative Instructions Under the PCT (and Chapter 10 of the PCT International Search and Preliminary Examination Guidelines), reversal of the Examiner's action in maintaining the Restriction Requirement is respectfully requested.

Conclusion

For the forgoing reasons, applicants request reversal of the Examiner's decisions not to extend the search, to make Final the Office Action of May 28, 2008, to deny entry of the amendments after Final submitted December 16, 2008, and to maintaining the Restriction Requirement.

The Commissioner is hereby authorized to charge any fees associated with this response or credit any overpayment to Deposit Account No. 13-3402.

Respectfully submitted,

/Brion P. Heaney/

Brion P. Heaney Reg. No. 32,542
Attorney/Agent for Applicant(s)

MILLEN, WHITE, ZELANO
& BRANIGAN, P.C.
Arlington Courthouse Plaza 1, Suite 1400
2200 Clarendon Boulevard
Arlington, Virginia 22201
Telephone: (703) 243-6333
Facsimile: (703) 243-6410

Attorney Docket No.: **MERCK-2723**

Date: February 9, 2009